

REMARKS

Reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Claim 1 has been amended with the amendments being supported at paragraph [0028] of the published PCT application, at the last sentence thereof.

The claims presently pending before the Examiner are 1-8 and 13.

Claims 1, 2 and 4-8 have been rejected under 35 USC § 103(a) as being unpatentable over Cotell et al. (WO 04/22513) in view of Antonov et al. (Laser Modification of Biocompatible Calcium Phosphate Coatings, *Lasers in Life Sciences*, 2000, Vol. 9, pp. 127-142). This rejection is respectfully traversed.

Cotell discloses a method of providing a flexible medical device with a bioactive coating by annealing an amorphous CaP coating deposited on said medical device. Cotell specifically addresses the problems associated with annealing a coating on a polymer substrate, which is temperature sensitive, as does the present invention.

Contrary to what the Examiner has asserted, however, Cotell is **not at all silent** regarding the particular wavelength of light used, as he advocates the use of specific types of lasers, each one having its own specific wavelength ranging from 197 nm (ArF) to 10,600 nm (CO₂). It is noted that the devices of Cotell are exclusively intended for use inside the body. Therefore, the Examiner's remark that it is well known that for "medical devices to be used inside the body, a wavelength of 200-300 nm is commonly used", is improper because it is not supported by the very prior art that the Examiner is relying on in his reasoning.

Admittedly, the most preferred laser according Cotell is the KrF laser with a wavelength of 248 nm, but there is absolutely no explanation provided for this preference.

Antonov discloses wavelengths within the range of 200-300 nm (and higher), but Antonov does not 'prescribe' this specific range when irradiating devices for implantation inside the body. Contrary to Cotell, Antonov does provide some further explanation and motivation with regard to the choice of the laser wavelength.

As explained in the background part of the present specification, Antonov teaches that, on polymeric substrates, peeling poses significant difficulties, which according to Antonov should be resolved by fine adjustment of the laser fluence, uniform energy distribution across the laser beam and by reverting to multipulse techniques. These suggestions are entirely reconcilable with the teachings of Cotell.

Hence, one of ordinary skill in the art at the time of the claimed invention would have combined the teachings of Cotell and Antonov and would simply have adhered to these teachings and would not have found any motivation whatsoever to revert to a wavelength well below 200 nm, such as to deviate from the specific teachings of both Cotell and Antonov.

Such a wavelength is simply not mentioned in either Cotell or Antonov and it, most certainly, is well outside the wavelength ranges that these documents do, in fact, disclose.

The 'motivation' relied upon by the Examiner is not derivable from either of the two (2) references, and the assertions are not supported at all by the facts and the evidence as can be inferred, for example, from the table set forth below¹. Based on said information, it is not at all seen why the ordinary skilled person who allegedly is seeking to increase safety, would have found any motivation to depart from the teachings of Cotell or Antonov and choose a laser of well below 200 nm wavelength. It is certainly not apparent which safety benefits the Examiner is relying upon.

¹ As obtained from the *Laser Safety Manual*, Case Western University (April 7, 2005), <https://www.case.edu/finadmin/does/RadSafety/LaserSOP.pdf>.

Spectral Wavelength	Eye	Skin
Actinic UV: Ultraviolet C (100-280 nm)	Cornea: photokeratitis	Erythema (sunburn) Skin cancer Aging of skin
Actinic UV: Ultraviolet B (280-315 nm)	Lens: photochemical cataracts Retina: blue light injury	Increased pigmentation
Near UV: Ultraviolet A (315-400 nm)	Lens: photochemical cataracts Retina: blue light injury	Pigment darkening Skin burns
Visible (400 nm-700 nm)	Retinal burns: thermal injury	Pigment darkening Photosensitive reactions Skin burns
Infrared A (760-1400 nm)	Cataracts and retinal burns	Skin burns
Infrared B (1400-3000 nm)	Cornea: burns Aqueous flare (fluorescence) Lens: cataracts	Skin burns
Infrared C (3000 nm-1.000 mm)	Cornea: burns	Skin burns

Also, the Examiner's assumption regarding costs of using lasers of different wavelengths is entirely lacking in substantiation, and, as yet, Applicants have been unable to collect any documentation that would allow for the verification of the Examiner's assertions.

It is therefore respectfully requested that the Examiner provide the evidence backing up his assertion or that he withdraw the rejection. It is submitted that an obviousness objection cannot be based solely on statements and assumption that are not verifiable.

In addition, it is noted that the Examiner's assertion that one of ordinary skill in the art would be motivated to make processing safer and less expensive must have been equally applicable for Cotell and Antonov, as well, both of which, however, fail to disclose wavelengths of well below 200 nm.

In summary, neither Cotell nor Antonov discloses a process of annealing an amorphous CaP coating by laser irradiation at well below 200 nm and the skilled person would not find any motivation in these documents in combination nor in his common general knowledge to revert to such wavelengths, for whatever reason.

The claimed invention, on the other hand, provides a significant, unexpected and unpredictable improvement over these prior art documents exactly *by reverting to such wavelengths*. An important aspect of the claimed invention is the recognition of a sharp decrease in transmission of light of wavelengths well below 200 nm in the amorphous CaP coating, as illustrated in Fig. 3 of the as-filed specification. Due to this characteristic, which was neither disclosed in nor derivable from the cited prior art documents, the use of laser irradiation of a wavelength well below 200 nm, such as the F₂ laser, provides a very significant advantage, especially where the substrate is heat labile, because less energy (heat) is transmitted to said substrate. Transmission of heat to the substrate causes problems such as deterioration of the substrate and damage of the interface of coating and substrate (peeling).

Both of the cited prior art documents clearly recognize the problems associated with annealing a CaP coating on a heat-labile substrate and discuss extensively all the process parameters that, according to the authors, could aid in reducing or eliminating these problems, without there being any suggestion of lowering the wavelength of the laser light to well below 200 nm. This strongly indicates that this solution must have been far from obvious, at least for these authors, which in view of the Applicants also (at least) qualify as 'persons of ordinary skill in the art'.

In summary, Cotell as well as Antonov address the problems for which the present invention has provided a solution, but fail to disclose or suggest this particular solution.

It is respectfully submitted that the claims distinguish over the combination of Cotell et al. in view of Antonov et al. Thus, the Examiner has failed to establish *prima facie* obviousness by a preponderance of the evidence. Since the rejection has clearly been overcome, its withdrawal is respectfully solicited.

Claims 3 and 13 have been rejected over Cotell et al. in view of Antonov et al. and further in view of Li et al. This rejection is respectfully traversed.

Dependent claims 3 and 13 distinguish over the combination of references advanced by the Examiner since the deficiencies in the teachings of the primary and secondary references detailed above are not ameliorated by Li et al. Accordingly, the § 103(a) rejection has been overcome and should be withdrawn.

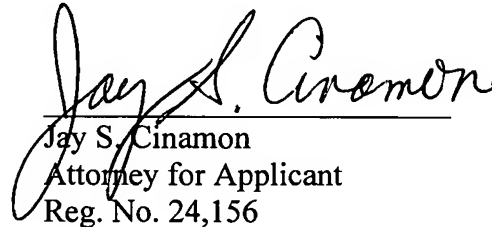
The issuance of a Notice of Allowance is solicited.

Please charge any fees which may be due and which have not been submitted herewith to our Deposit Account No. 01-0035.

Respectfully submitted,

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